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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/090,672	06/04/1998	TETSUYOSHI ISHIWATA	766.21	4139
5514	7590	10/31/2003	EXAMINER	
FITZPATRICK CELLA HARPER & SCINTO 30 ROCKEFELLER PLAZA NEW YORK, NY 10112				WOITACH, JOSEPH T
ART UNIT		PAPER NUMBER		
		1632		

DATE MAILED: 10/31/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/090,672 Examiner Joseph T. Woitach	ISHIWATA ET AL. Art Unit 1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### **Status**

- 1) Responsive to communication(s) filed on 05 August 2003.
- 2a) This action is **FINAL**.                    2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### **Disposition of Claims**

- 4) Claim(s) 1,18,19,22 and 23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) Claim(s) 23 is/are allowed.
- 6) Claim(s) 1,18,19 and 22 is/are rejected.
- 7) Claim(s) \_\_\_\_\_ is/are objected to.
- 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### **Application Papers**

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on \_\_\_\_\_ is/are: a) accepted or b) objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on \_\_\_\_\_ is: a) approved b) disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

#### **Priority under 35 U.S.C. §§ 119 and 120**

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All    b) Some \* c) None of:
1. Certified copies of the priority documents have been received.
2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_ .
3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### **Attachment(s)**

- 1) Notice of References Cited (PTO-892)                    4) Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_ .
- 2) Notice of Draftsperson's Patent Drawing Review (PTO-948)                    5) Notice of Informal Patent Application (PTO-152)
- 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s) 7/7/03 .                    6) Other: \_\_\_\_\_ .

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### **DETAILED ACTION**

This application is a continuation in part of PCT/JP97//04468, filed December 5, 1997, which claims benefit to foreign application HEI. 8-325763, filed December 5, 1996 in Japan.

Applicants' amendment filed August 5, 2003 has been received and entered. Claims 1, 22 and 23 have been amended. Claims 1, 18, 19, 22 and 23 are pending and currently under examination.

#### ***Information Disclosure Statement***

The information disclosure statement filed July 7, 2003 complies with 37 CFR 1.98. A signed copy of the 1449 form is included with the instant action.

#### ***Claim Objections***

Claim 1 is objected to because of the following informalities: The recitation contained within the parenthesis describing 1x SSC is not necessary. The formulation of SSC is a well known in the art as described in and supported by the specification. Reciting it in the claim in part infers that other formulations of SSC may exist.

Appropriate correction is required.

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***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1, 18 and 19 rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is withdrawn.

Amendments to claim 1 to encompass polynucleotide sequences comprising only specific SEQ ID NOs has obviated the basis of the rejection.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1, 18, 19 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Initially, it is noted that the claim amendments have addressed and obviated the specific rejections previously set forth.

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Claim 1 is unclear and confusing in the recitation of the hybridization conditions. The amended claims appear to encompass polynucleotide sequences comprising SEQ ID NOS: 1-6, 9-12 and 39-42, and it is unclear how the hybridization conditions relate to the sequences encompassed by the claim. It is unclear if the conditions are intended to provide structural or functional limitations to the claims, or if they are simply redundant characterizations of SEQ ID NOS: 39-42. Further, it is unclear if large sequences which comprise SEQ ID NOS: 39-42 but do not hybridize would be encompassed by the claim. Finally, it is unclear which five polynucleotides, SEQ ID NOS: 1-5 are used, but only four polynucleotides are set forth at the end of (ii). It is noted that each SEQ ID NOS: 1-5 are unrelated to each other, but that SEQ ID NOS: 1-4 are related to SEQ ID NOS: 39-42, respectively. The claims are indefinite because the metes and bounds of the relationship of the hybridization conditions to the specific sequences encompassed by the claims are not clearly set forth. Dependent claims 18 and 19 are included in the rejection because they fail to further clarify the basis of the rejection. Clearly setting forth the specific sequences intended to be encompassed by the claim would obviate the basis of the rejection.

Claim 22 is unclear in the recitation of “among nucleotide sequences of SEQ ID NOS: 1-6 and 9-12...” because there are not any continuous sequence of 10-50 residues shared between the sequences. Further, because SEQ ID NOS: 1-6 and 9-12 are not related only specific combinations of potential primers from one contiguous sequence as set forth as a SEQ ID NO

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would be functional in the assay, and one could not mix primers derived from among the various SEQ ID NOS: 1-6 and 9-12.

***Conclusion***

As noted in the previous office action, claim 23 is allowed. Claims 1, 18, 19 and 22 are free of the art of record because the art fails to teach polynucleotide sequences encompassed by the instant claims. Further, the art fails to teach that these polynucleotide sequences correlate to genes which demonstrate an increased expression in the leukocytes of patients suffering from IgA nephropathy, however the claims are subject to other rejections.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Joseph T. Woitach

*Joe Woitach  
1632*